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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,094	04/16/2004	Srinivasa Madhyastha	14233.16USU1	9255

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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/826,094	MADHYASTHA, SRINIVASA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 16-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office action is in response to the amendment filed August 2, 2005. **Claims 1-15 and 34** are presently pending and under examination.

#### ***Restriction requirement***

This application contains claims 16-34 drawn to an invention nonelected with traverse in Paper filed January 13, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Withdrawal of Objections and Rejections***

The objections and rejections not explicitly restated below are withdrawn.

#### ***Maintenance of rejections***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

**Claims 1-3, 5-8, 10-12** are remain under 35 U.S.C. 103(a) as being unpatentable over Raad et al. United States Patent 5,688,516 in view of Filho et al., 1994 (cited in the IDS filed August 27, 2004).

**Claims 1, 5-10 and 35** remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mebes et al. United states Patent 4,845,256 in view of Filho et al., 1994 (cited in the IDS filed August 27, 2004).

**Claim 1-2, 4-9 and 13-14** remain rejected under 35 U.S.C. 103(a) as being unpatentable over Berry US2002/0133169 in view of Filho et al., 2002 (cited in the IDS filed August 27, 2004).

**Claims 1 and 15** remain rejected under 35 U.S.C. 103(a) as being unpatentable over Raad et al. United States Patent 5,688,516 in view of Filho et al., 1994 (cited in the IDS filed August 27, 2004). and further in view of Chinn et al. United States Patent 6,528,107.

The above rejections were explained in the Office action.

***Response to applicant's arguments***

In regards to the rejection of claims under 35 U.S.C. 103(a) applicants assert that there is no reasonable expectation of success nor do the prior art references teach or suggest all the claim limitations. Applicants assert further that in each of the four separate rejections under 35 U.S.C. 103(a) for alleged obviousness at least one of the cited art references fails to teach antibiofilm properties. Specially , Mebes et al., Berry and Filho et al. do not teach anti-biofilm properties, but rather only teach antimicrobial properties. Biofilms can resist antimicrobial treatments, or to a much larger degree, than planktonic cells of individual microorganisms that comprise a biofilm. In fact, biofilms are inherently "much less susceptible to antibiotics" and "can evade antimicrobial challenges by multiple mechanisms." A demonstration of antimicrobial properties does not necessarily translate to anti-biofilm properties. As such, the Examiner has not established a reasonable expectation of success in any of the four prior art combinations used to reject the claims under 35 U.S.C. 103(a).

Applicants also assert that certain synergistic properties with regards to combining specific compounds such as oPDM, PyrM and PS, exhibited in the examples and figures, indicate unexpected results with regards to inhibiting microbial biofilms on devices.

Applicants' assertions have not been found persuasive. The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. Furthermore, if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court and the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant (M.P.E.P 2144).

The prior art has clearly established that the individual components of the composition of the present invention, when combined have antimicrobial properties, which the applicants themselves have acquiesced to in the response filed August 2, 2005. Therefore, the fact that applicants have recognized another advantage, which

would flow naturally from following the suggestion of the prior art, cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

It is necessary to point out that the mentioned limitation/property that the applicants rely upon for their arguments appears in the preamble of the claim and in most situations not given patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is also important to point out that the limitation "inhibiting bacterial biofilms" is a recitation of the intended use of the claimed invention and must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the present case, since the combined components of the composition taught by the prior art are identical to the composition of the invention then it would be logical to assume that the composition taught by the prior art would also have the same function, which is to inhibit bacteria biofilms on devices.

Finally with regards to the unexpected synergistic result of combining specific compounds such as oPDM, PyrM and PS, it must be noted that independent claim 1 is not presently commensurate within the scope of the unexpected synergistic results.

Applicants are more than welcome to amend the claims in order to clarify the scope of the claims with regards to unexpected results.

***Conclusion***

No claims are allowed

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

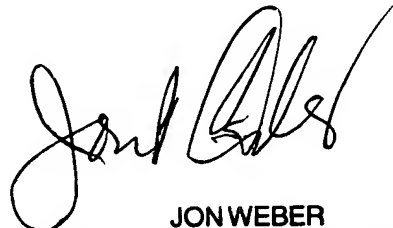
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert B. Mondesi  
Patent Examiner  
Group 1653  
09-21-08

  
JON WEBER  
SUPERVISORY PATENT EXAMINER